K001281

JUN 1 2 2001

510(k) Submission, Geratherm Babywatch Temperature monitoring Device,
R.G. Enterprises, Inc. Southfield, MI 48075.

The following is a Summary of the Geratherm Babywatch Temperature Monitoring Device substantial equivalence and safety and efficacy.

Classification Name: General Hospital

Common / Usual Name: Electronic thermometer

Proprietary Name: Geratherm Babywatch Temperature Monitor

Classification: FLL - C. F. R 880.2910

Performance Standards: No Performance Standards are in effect for this devise.

Predicated Devise: Diatek Thermometer, K833568, and Deep Body Thermometers Limited, pre 1976 device

Parameter	Babywatch Digital Monitor	Deep Body Thermometers Limited	Diatek Digital Thermometer
Intended Use	Baby body temperature	Patient body temperature	Patient temperature
Temperature Range	62.6° F (17.00°C)-113.0° F (45.00°)	78.8° F (26°C)-107.6° F (42°C)	Full Range Unknown
Display Type	Digital	Digital	Digital
Display Resolution	± 0.1 C	± 0.1 C	± 0.1 C
Warm-up Time	3 seconds	30 minutes	30 minutes
Accuracy	± 0.1 C ± 0.2 F	0.3 C	0.3 C
Counts Up and Down	Yes	Yes	Up only
Ambient Temperature Environment	Less than temperature being taken	Less than temperature being taken	Less than temperature being taken
Skin surface probe	Groin or arm pit	yes	Mouth or arm pit

Power Supply	Battery	Battery or Mains	Battery
Battery Charger	No	Yes	Yes
Single Patient Probe	Yes	Yes	Yes
Shipped Sterile	No	No	No
Microprocessor	No	No	Unknown
Alarms	Yes	No	No
FDA "K" Number		Pre 1976 device	K833568

Indications	Measures at 8 preset intervals, displays current temperatures, stores and can display up to 70 temperature readings, upper and lower temperature alarm settings.
Contraindications	Will not provide valid data if ambient temperatures are greater than patient body temperature. Requires only 3 second warm-up before achieving accurate readings.
Non-clinical test	Non-clinical test included comparison with temperature standard.
Conclusions	The Geratherm Babywatch Temperature Monitor is equivalent in safety and efficacy to its predicate devises.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 12 2001

Geratherm AG
C/O Mr. Ed Holter
R.G. Enterprises, Incorporated
2000 Town Center, Suite 1900
Southfield, Michigan 48075-2645

Re: K001281
Trade/Device Name: Geratherm Babywatch Temperture Monitor
Regulation Number: 880.2910
Regulatory Class: II
Product Code: FLL
Dated: March 20, 2001
Received: March 21, 2001

Dear Mr. Holder:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) NUMBER (IF KNOWN): K001281

DEVICE NAME: Geratherm Babywatch Temperature Monitor

INDICATIONS FOR USE:

Babywatch Temperature Monitor is for measuring a baby's temperature and storing data at adjustable preset intervals. The Babywatch can continuously monitor the body temperature and store up to 70 temperature readings. The Babywatch features a high and low adjustable temperature alarm setting. A beeping alarm will sound if baby's temperature exceeds the high temperature setting or falls below the low temperature setting. The Babywatch allows parent or doctor to view stored temperature information.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription use_____ OR Over-The-Counter-Use X
(Per 21 CFR 801. 109) (Optional Format 1-2-96)

Patricia Cucuzzella
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K001281